REMARKS

Claim Rejections – 35 U.S.C. § 103

Claims 1-13 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Reynolds (US 5,364,369). According to the Examiner, Reynolds discloses a syringe (see at least Figures 1-16) comprising a syringe barrel (6) having an elongated body and chamber, an open proximal end, a distal end and a frusto-conically shaped tip (5) extending from the distal end having a tip passageway therethrough in fluid communication with the chamber, a rubber stopper (6) in fluid-tight engagement inside the barrel, an elongated plunger rod (10) defining a longitudinal axis and extending proximally from the stopper through the open end, and a flange (not numbered) at the proximal end, a tip cap (4) for sealing the passageway, and a flush solution (A) in the chamber, the inside diameter of the of the chamber designed to produce a low pressure, wherein the chamber contains no more than 3.5 ml of solution, and the solution can be saline or heparin lock, wherein the syringe is packaged in a sterile package as is well-known in the art, and wherein the barrel can include indicia as is well-known in the art. According to the Examiner, Reynolds discloses making the barrel of the syringe wider and shorter than a standard syringe, but does not disclose that the chamber has a diameter of 13.5 mm and a length of 57 mm. However, the Examiner states that these dimensions are deemed to be matters of design choice and are not given much patentable weight. Thus, according to the Examiner, it would have been *prima facie* obvious to one of ordinary skill in the art to modify Reynolds with the dimensions recited in claims 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art Reynolds.

Applicants respectfully traverse this basis for rejection.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), *viz.*, (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 985, 180 USPQ 580 (CCPA 1974). Furthermore, although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

Claim 1

Claim 1 is directed to an I.V. flush syringe assembly comprising, *inter alia*, a) a syringe barrel having an elongated body defining a chamber having flush solution therein and a frusto-conical tip having passageway therethrough in fluid communication with the

chamber, the chamber having an inside diameter of at least 13.5 mm (0.53 inch), the length of said chamber being no more than 57 mm (2.25 inches); b) a stopper; c) a plunger rod; and d) a tip cap, wherein the pressure of the flush solution injected through the passageway is less than 40 psi when 10 pounds of force is applied to the plunger rod. By providing an inside diameter of at least 13.5 mm, which is on the order of a traditional 10 mL flush syringe, fluid pressures are maintained at or below those produced by a traditional 10 mL flush syringe assembly. *See* page 2, paragraph 0004. A major advantage of such a flush syringe assembly is that the fluid pressure will be only about one-third of the fluid pressure if a prior art 3 ml syringe were being used with the same force being applied to the plunger rod. The reduced pressure makes it easier for the user to determine if the catheter is open and reduces the possibility of dislodging a clot or rupturing the catheter. In addition, if larger volume syringes having the same diameter are used, the general feel of the syringe and the technique will remain consistent from syringe to syringe so that the feel and the touch and the forces applied in flushing the catheter with a 3 ml syringe of the present invention are the same as a 10 ml syringe having the same diameter. *See* page 8, paragraph 0034. In this way, a family of flush syringes can be provided, each with diameters on the order of a traditional 10 mL flush syringe but containing different amounts of flush solution, thus allowing optimal pressure distribution to be achieved with all volumes. *See* page 10, paragraph 0041.

In contrast to the flush syringe assembly of claim 1, the syringe system disclosed in Reynolds is for delivery of a pharmaceutical medicament to a patient. The syringe system, shown in Figures 1 and 2, comprises an open-ended vial 6 in which is stored medicament A. The bottom wall of the vial is replaced with axially movable piston 8.

The vial is converted into a prefilled syringe by applying outer cap 2 and attaching cylindrical plunger sleeve 8 to piston 8. If medicament A is in dry form, capsule 14 containing liquid medium B may be placed in plunger sleeve 8 to dissolve medicament A. *See* col. 6, line 67 to col. 8, line 36.

The Examiner acknowledges that Reynolds does not disclose that the chamber (i.e., vial) has a diameter of at least 13.5 mm and a length of no more than 57 mm, but states that such dimensions are merely matters of design choice which are not given much patentable weight. However, the Examiner has failed to cite any evidentiary to support such a conclusion. *See In re Weiss*, Appeal No. 2005-2572, for U.S. Pat. Appl. No. 10/268,809, at 11 (BPAI 2005) ("The examiner deals with these shortcomings [of the prior art] by submitting that '[the missing element] is deemed to be a design consideration that fails to patentably distinguish over the prior art . . . , but has not cited any evidentiary basis to support this conclusion."); *In re Swope*, Appeal No. 2004-1052, 2004 Pat. App. LEXIS 30, at *7-8 (BPAI Jul. 22, 2004) ("To supply [the] omission in the teachings of Winninger, the examiner made a determination . . . that this difference would have been obvious to an artisan as a matter of engineering design choice. However, this determination has not been supported by any evidence that would have led an artisan to arrive at [the claimed] endless drive belt . . . ."). By relying on "design choice" to supply the missing subject matter, the Examiner has obfuscated any factual reasoning behind the obviousness rejection. *See in re Dove*, Appeal 2007-4317, 2008 Pat. App. LEXIS 6, at *15 (BPAI Feb. 28, 2008) ("[T]he old phrase 'design choice' in obviousness rejections [] masks rather than elucidates the reasoning behind the rejection.") (Torczon, J., concurring). The Examiner has failed to point to anything in Reynolds or the art in

general that would have led one of skill in the art to modify the dimensions of a traditional flush syringe to arrive at the claimed invention. Stating that such modifications are merely matters of "design choice" is precisely the type of conclusory statement that the Supreme Court has counseled against in obviousness determinations. *See KSR*, 127 S. Ct. at 1741 ("'Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'") (quoting *Kahn*, 441 F.3d at 988); *see also Swope*, 2004 Pat. App. LEXIS 30, at 8* ("A broad conclusory statement regarding the obviousness of modifying a reference, standing alone, is not 'evidence.'"); *In re Schaefer*, Appeal No. 1998-0801, for U.S. Pat. Appl. No. 08/557,979, at 4 (BPAI 1998) ("Like appellants, we find the examiner's reliance on 'design consideration' to provide for the many structural differences between the apparatus of Bernhardt and that defined in the claims on appeal to be entirely untenable, fraught with speculation and conjecture, and completely without any evidential support.").

A proper review of Reynolds indicates that it would have failed to suggest to one skilled in the art the dimensions of the syringe barrel in the claimed I.V. flush syringe assembly. As noted above, Reynolds is directed to administration of medicaments by injection. Reynolds states that the prefilled syringe has significant advantages over conventional prefilled syringes in that the vial may be filled using conventional vial filling equipment, and yet may be utilized directly instead of requiring its contents to be transferred to a syringe prior to use as has been conventional in the use of vials. *See* col. 8, lines 21-27. To achieve this advantage, Reynolds states that the overall height of the vessel exceeds the external diameter of the rim of its base by a factor sufficiently small

that it remains stable when passing through conventional vial filling and capping equipment utilized to fill and cap the vial. *See* col. 7, lines 15-21. According to Reynolds, this factor preferably does not exceed 2.5, but can be increased by means discussed with reference to Figures 17-21. *See* col. 7, lines 21-24. With reference to those figures, Reynolds again notes that the practical limit of the height to diameter ratio is set entirely by the requirement that the vials can be conveyed through a conventional vial filling and capping machine in a sufficient stable manner to permit reliable operation of the machine, and states that the vial has an outside diameter of approximately 3 cm (30 mm) and a height of 12.8 cm (128 mm). A height of 14 cm (140 mm) is believed to approach the practical limit for stability. *See* col. 15, lines 12-20.

Thus, Reynolds teaches that the ratio of length to the outer diameter of the vial is dictated by stability when passing through conventional vial filling equipment, with lengths up to ***140 mm*** being suitable as long as the ratio of length to ***outer*** diameter does not exceed a maximum of ***4.67*** (140 mm/30 mm). In contrast, the length of the claimed syringe barrel is no more than ***57 mm***, with a maximum possible ratio of length to ***inner*** diameter being ***4.22*** (57 mm/13.5 mm). Nothing in Reynolds would have suggested to one skilled in the art to modify the dimensions of the vial to arrive at the dimensions of the claimed syringe barrel. As recited in claim 1, the claimed dimensions provide an ***I.V. flush syringe*** assembly which achieves a fluid pressure of less than 40 psi when 10 pounds of pressure is applied to the flush solution contained in the syringe barrel. Again, Reynolds is directed to administration of medicaments by injection. Reynolds makes no reference to I.V. flush procedures, or any of the problems associated with such procedures, such as dislodging a clot or rupturing a catheter. Indeed, Reynolds does not

use the words "catheter," "flush," "saline" or "heparin" at all. Reynolds teaches that the dimensions of the vial are dictated by stability when passing through conventional vial filling equipment. As such, one of skill in the art would not look to the medicament syringe of Reynolds to provide guidance for solving the problem of unacceptable fluid pressure in traditional flush syringes. *See In re Gal*, 980 F.2d 717, 719 (Fed. Cir. 1992) ("The Board held that Gal had simply made an obvious design choice. However, the different structures of Gal and Matsumura [the cited prior art] achieve different purposes.").

Furthermore, relying on the dimension ranges in Reynolds (i.e., ratio of length to ***outer*** diameter up to 4.67, with the ratio of length to ***inner*** diameter naturally being greater) would yield numerous syringe embodiments with unacceptable fluid pressure (should one be so inclined to use the syringe of Reynolds as a flush syringe, which would directly contravene the teachings of the reference), precisely the problem addressed by the claimed invention. One reading Reynolds would ***increase*** the length/diameter ratio of the vial up to the point of stability loss to maximize medicament capacity, as opposed to ***decreasing*** the length/diameter ratio to reduce flush solution pressure, as taught in the instant application. In no way can it be said that it was merely a matter of design choice to arrive at the claimed dimensions. *See In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result- effective variable.); *In re Chu*, 66 F.3d 292, 299 (Fed. Cir. 1995) ("Chu's evidence regarding the violent 'snapping' action during

pulse-jet cleaning, the difficulty in stitching compartments including the capacity to withstand high temperatures, and problems encountered from variable path lengths due to settling of catalyst particles militates against a conclusion that placement of the SCR catalyst is merely 'design choice.'"); *In re Cassel*, Appeal No. 2002-1893, 2002 Pat. App. LEXIS 203, at *8 (BPAI Jul. 25, 2002) ("Thus, the obviousness rejection . . . is reversed because the skilled artisan armed with the stiff and nonelastic strap teachings of O'Dwyer certainly would not have resorted to 'design choice' to choose a material that performs in an opposite manner to the material specifically chosen by O'Dwyer.").

Applicants submit that by relying on "design choice," the Examiner has impermissibly used hindsight to reconstruct the claimed invention from an unrelated prior art syringe. *See In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967) ("The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis."). When viewed under the proper test for obviousness, it is clear that the dimensions of the claimed I.V. flush syringe assembly were not the result of mere "design choices," but rather an unobvious solution to a problem not identified or solved in the cited prior art. *See In re Pelosi, Jr.*, Appeal No. 1999-1813, for U.S. Pat. Appl. No. 08/801,010, at 5-6 (BPAI 2001) ("[T]he specific limitation regarding the taper of the appellant's device [with the claimed dimensions] is not merely a matter of design choice, as the examiner has stated, but constitutes a solution to a problem existing in the art.").

Accordingly, Applicants submit that claim 1 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 2

Claim 2 is directed to the flush syringe assembly of claim 1, wherein the length of the syringe barrel is in the range of 38.1 mm (1.5 inches) and 44.5 mm (1.75 inches). Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987). Because one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1, it necessarily follows that one of ordinary skill in the art would also not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the narrower length range recited in claim 2.

Accordingly, Applicants submit that claim 2 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 3

Claim 3 is ultimately directed to the flush syringe assembly of claim 1, wherein the chamber contains no more than 3.5 ml of flush solution. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 1, one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1. Furthermore, as discussed above, because Reynolds is directed to a syringe for injecting medicaments, there is no teaching or suggestion of flush solution anywhere in the reference.

Accordingly, Applicants submit that claim 3 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 4

Claim 4 is directed is directed to the flush syringe assembly of claim 1, wherein the flush solution is selected from the group consisting of saline flush solution and heparin lock flush solution. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 1, one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1. Furthermore, as discussed above with respect to claim 3, Reynolds does not teach or suggest placing any flush solution, let alone saline or heparin, in the syringe vial.

Accordingly, Applicants submit that claim 4 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 5

Claim 5 is directed to the flush syringe assembly of claim 1, wherein the syringe assembly is contained in a package which provides a tamper evident barrier surrounding the syringe assembly. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 1, one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1. Furthermore, the Examiner has pointed to nothing in Reynolds or the art in

general that teaches or suggests a package which provides a tamper evident barrier. *See Smiths Indus. Med. Sys. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356 (Fed. Cir. 1999) ("That knowledge *may* have been within the province of the ordinary artisan does not in and of itself make it so, absent clear and convincing evidence of such knowledge.") (emphasis in original).

Accordingly, Applicants submit that claim 5 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 6

Claim 6 is directed to the flush syringe assembly of claim 1, wherein the syringe assembly is contained in a package which provides a sterile barrier surrounding the syringe assembly. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 1, one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1. Furthermore, the Examiner has pointed to nothing in Reynolds or the art in general that teaches or suggests a package which provides a sterile barrier. *See Smiths*, 183 F.3d at 1356.

Accordingly, Applicants submit that claim 6 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 7

Claim 7 is directed to the flush syringe assembly of claim 1, further including volume measuring indicia on the barrel. Where an independent claim is valid over cited

art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 1, one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1. Furthermore, the Examiner has pointed to nothing in Reynolds that teaches or suggests providing indicia on a syringe barrel. *See Smiths*, 183 F.3d at 1356.

Accordingly, Applicants submit that claim 7 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 8

Claim 8 is ultimately directed to the flush syringe assembly of claim 1, further including volume measuring indicia on the barrel which indicates the stopper position for a chamber volume of about 3 ml. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 1, one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1. Furthermore, as discussed above with respect to claim 7, the Examiner has pointed to nothing in Reynolds that teaches or suggests providing indicia on a syringe barrel, let alone the specific 3 ml indication recited in claim 8. *See Smiths*, 183 F.3d at 1356.

Accordingly, Applicants submit that claim 8 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 9

Claim 9 is directed to the flush syringe assembly of claim 1, wherein the stopper is made of material selected from the group of natural rubber, synthetic rubber, thermoplastic elastomers and combinations thereof. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 1, one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1.

Accordingly, for at least the reasons given above with respect to claim 1, Applicants submit that claim 9 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 10

Claim 10 is directed to the flush syringe assembly of claim 1, wherein the inside diameter of the chamber is 14.43 mm (0.568 inches). Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1, it necessarily follows that one of ordinary skill in the art would also not have

resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the specific inside diameter recited in claim 2.

Accordingly, Applicants submit that claim 10 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 11

Claim 11 is directed to the flush syringe assembly of claim 1, wherein the plunger rod flange is smaller than the open proximal end of the barrel when measured in a direction perpendicular to the longitudinal axis so that the plunger rod flange does not extend radially beyond the barrel. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 1, one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1.

Furthermore, Reynolds would not have suggested to one of skill in the art a plunger rod flange that is smaller than the open proximal end of the barrel so that the plunger rod flange does not extend radially beyond the barrel following fluid delivery. As explained in the instant application, the use of such a plunger rod prevents inadvertent or accidental movement of the plunger rod in a proximal direction following fluid delivery, thereby avoiding negative pressure in the line which can cause blood reflux into a catheter lumen. *See* page 9, paragraph 0036. The Examiner has pointed to nothing in Reynolds that teaches or suggests such a plunger rod. Indeed, Figure 6 of Reynolds clearly shows flange 26 of plunger sleeve 10 wider than the base of vial 6, such that it

would extend radially beyond the vial following medicament delivery. Again, because the syringe in Reynolds is designed for administration of medicaments, and not for delivering I.V. flush solutions, one of skill in the art would not have sought to modify the plunger flange as defined in claim 11 to prevent blood reflux associated with I.V. flush syringe assemblies. *See Ex parte Beigel*, Appeal No. 2005-0171, for U.S. Pat. Appl. No. 10/064,380, at 21 (BPAI 2003) ("Given the fact that [prior art references] Chatelot and Kurusu are directed to different problems in the communication art, with disparate solutions to such problems, it is our view that any attempt to combine them could come only from Appellants' own disclosure and not from any teaching or suggestion in the references themselves.").

Accordingly, Applicants submit that claim 11 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 12

Claim 12 is directed to the flush syringe assembly of claim 1, wherein the stopper and plunger rod are dimensioned so that when the plunger rod flange contacts the proximal end of the barrel there is a space between at least a portion of the distal end of the stopper and the distal wall of the barrel. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 1, one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1.

Furthermore, Reynolds would not have suggested the one of skill in the art a stopper and plunger rod dimensioned so that when the plunger rod flange contacts the proximal end of the barrel there is a space between at least a portion of the distal end of the stopper and the distal wall of the barrel. As explained in the instant application, this configuration prevents the stopper from being excessively compressed against the distal chamber wall, thereby preventing the stopper from expanding following fluid delivery and possibly pulling fluid back from the catheter and allowing blood to enter the catheter tip. *See* page 9, paragraph 0037. The Examiner has pointed to nothing in Reynolds that teaches or suggests such a configuration. Indeed, the dimensions shown in Figure 6 of Reynolds suggest that piston 8 would contact the distal wall of vial 6 (and thus no space would be present) when flange 26 of plunger sleeve 10 contacts the base of vial 6. Again, because the syringe in Reynolds is designed for administration of medicaments, and not for delivering I.V. flush solutions, one of skill in the art would not have sought to modify the dimensions of the stopper and plunger rod as defined in claim 12 to prevent blood reflux associated with I.V. flush syringe assemblies. *See Beigel*, Appeal No. 2005-0171, at 21.

Accordingly, Applicants submit that claim 12 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

Claim 13

Claim 13 is directed to the flush syringe assembly of claim 1, wherein the plunger rod includes a threaded extension projecting from the distal end of the plunger rod and the stopper defines a threaded recess which engages with the threaded extension of the plunger rod. Where an independent claim is valid over cited art, *a fortiori* any claim

dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 1, one of ordinary skill in the art would not have resorted to "design choice" to modify the medicament syringe of Reynolds to arrive at an I.V. flush syringe assembly having the dimensions recited in claim 1.

Accordingly, for at least the reasons given above with respect to claim 1, Applicants submit that claim 13 is not unpatentable over Reynolds, and reconsideration of this basis for rejection is respectfully requested.

CONCLUSION

It is believed that claims 1-13 are now in condition for allowance, early notice of which would be appreciated. If any additional fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 02-1666. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

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By: /Scott S. Servilla, Reg. #40806/
Scott S. Servilla
Reg. No. 40,806
Attorney for Applicants
Tel.: (732) 815-0404

BECTON, DICKINSON AND COMPANY
1 Becton Drive
Franklin Lakes, New Jersey 07417